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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Minority Health.

ACTION: Notice.

SUMMARY: The Department of Health and Human Service (HHS), Office of the Secretary, Office of Minority Health (OMH) announces the publication of the final enhanced *National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care*, known as the enhanced National CLAS Standards. In developing the enhanced National CLAS Standards, OMH undertook the National CLAS Standards Enhancement Initiative. From 2010-2012, this initiative included input from a National Project Advisory Committee composed of subject matter experts representing public, private and government sectors, regional public meetings, public comment period, and a systematic literature review. The enhanced National CLAS Standards, including a brief background summary of the development process and public comment period, are printed below.

DATES: The final enhanced *National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care* will be available beginning **[INSERT DATE THAT THIS NOTICE WILL APPEAR IN THE FEDERAL REGISTER]**.

ADDRESSES: The final enhanced *National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care* can be found online at www.thinkculturalhealth.hhs.gov .

FOR FURTHER INFORMATION CONTACT: CDR Jacqueline Rodrigue, Deputy Director, Office of Minority Health, Department of Health and Human Services, 1101 Wootton Parkway, Suite 600, Rockville, MD 20852. Attn: Enhanced National CLAS Standards. Telephone: (240) 453-2882.

SUPPLEMENTARY INFORMATION: In 2001, the HHS OMH published the *National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health Care*, known as the original National CLAS Standards, to address inequities that existed in the provision of health services, and to make these services more responsive to the individual needs of all patients and consumers. The original National CLAS Standards resulted from extensive research, discussions, input from stakeholders across the country, and offered a practical framework for the implementation of services and organizational structures that helped health care organizations and providers become more responsive to culturally and linguistically diverse communities. For the past decade, the original National CLAS

Standards have served as catalyst and conduit for efforts to improve the quality of care and achieve health equity.

The HHS OMH undertook the National CLAS Standards Enhancement Initiative from 2010 to 2012 to recognize the nation's increasing diversity, to reflect the tremendous growth in the fields of cultural and linguistic competency over the past decade, and to ensure relevance with new national policies and legislation, such as the Affordable Care Act. A decade after the publication of the original National CLAS Standards, there is still much work to be done. Racial and ethnic disparities in health and health care remain a significant public health issue, despite advances in health care technology and delivery, even when factors such as insurance coverage, income, and educational attainment are taken into account. Cultural and linguistic competency strives to improve the quality of care received and to reduce disparities experienced by racial and ethnic minorities and other underserved populations. Through the National CLAS Standards Enhancement Initiative (Enhancement Initiative), a new benchmark is being established for culturally and linguistically appropriate services to improve the health of all individuals.

The Enhancement Initiative followed the same development process as the original National CLAS Standards project in 1999-2001. The development process had three major components: (1) input from a National Project Advisory Committee comprised of subject matter experts representing public, private, and government sectors; (2) regional public meetings, public comment period; and (3) a systematic literature review. The goals of the Enhancement Initiative were to update the original National CLAS Standards in order to reflect the advancements of the

past decade, expand their scope, and improve upon their clarity in order to encourage more widespread understanding and implementation. The Enhancement Initiative also sought to develop a product that could assist individuals and organizations in the implementation of the enhanced National CLAS Standards.

Public Comment Period and Regional Public Meetings

As part of the National CLAS Standards Enhancement Initiative, OMH invited the public to submit comments on the original National CLAS Standards in late 2010, with the purpose of increasing public awareness of the National CLAS Standards. The announcement of the public comment period appeared in the Federal Register published on September 23, 2010 (75 Fed.

Reg. 57957 – 58), at

www.thinkculturalhealth.hhs.gov/CLCCHC/HealthNews/FederalRegister_CLAS.pdf.

The Federal Register announcement highlighted the various ways in which the public could provide comment, including submitting comments via an online portal, or submitting letters directly to OMH and/or its support team at SRA International, Inc. Individuals and organizations were encouraged to review the original National CLAS Standards and send written and/or online public comments during a 103-day period between September 20, 2010, and December 31, 2010. Over 500 individuals and 90 organizations participated in the public comment period.

Concurrent with the public comment period, three in-person regional public meetings were convened. The purpose of the regional public meetings was to gather and solicit detailed feedback from interested individuals and organizations that would complement and enhance the

public comments received by OMH through online and written submissions. These three public meetings were held on October 22, 2010, in Baltimore, Maryland; November 4, 2010, in San Francisco, California; and on November 15, 2010, in Chicago, Illinois. The total number of attendees for all three meetings was approximately 100 individuals from different organizations. The project team recorded and transcribed all three meetings. A qualitative theme analysis of the public meetings' transcripts was completed to determine relevant themes.

Analysis and Response to Public Comments Meetings on the enhanced National CLAS Standards

The following themes arose from the comments heard across the three public meetings.

The enhanced National CLAS Standards should:

- Encompass a broad definition of culture to include religion and spirituality; lesbian, gay, bisexual, and transgender community individuals; deaf and hearing impaired individuals; and blind and vision impaired individuals
- Incorporate the areas of patient satisfaction and safety
- Address issues of health literacy
- Establish congruency with other standards in the field
- Be action oriented
- Reflect advancements in terminology, technology, and more, including medical homes, electronic health records, and language access.

Analysis and Response to Written and Online Comments on the enhanced National CLAS Standards

A series of Likert-type statements were posed to those responding via the online portal and written submissions, and respondents were asked to indicate the degree to which they agreed or disagreed with each statement. Examples of the statements and responses are as follows:

1. “The National CLAS Standards meet my needs.”

Fifty-nine percent (59%) of the respondents either strongly agreed or agreed with the statement that the original National CLAS Standards met their needs as someone who works to improve the health of diverse communities. In a follow-up question, “In order for the CLAS Standards to meet my needs, the following enhancements would need to be made:” 29%, (n=51) of the respondents requested additional resources (e.g., additional training, funding, guides). In addition, 13% (n=24) requested CLAS enforcement mechanisms, 7% (n=13) requested promotion (i.e., need for increased awareness), 7% (n=13) requested increased clarity, and 7% (n=12) requested increased inclusivity of the populations addressed.

2. “I believe the National CLAS Standards [as a whole] should be revised”

Forty-eight percent (48%) of respondents either strongly agreed or agreed with the statement that the CLAS Standards should be revised. In a follow-up question, “I believe with revisions my utilization of the CLAS Standards will...” 29% (n=103) indicated that their utilization of the CLAS Standards would increase upon revision, while 25% (n=88) indicated that their utilization would stay the same. Similarly, 32% (n=113) of respondents indicated their belief that

their organization's utilization of the CLAS Standards would increase upon revision.

After December 31, 2010, when the public comment period ended, the project team analyzed the public comments received from all sources, including the 90 organizations that submitted online or written public comments. The following overarching themes emerged:

The enhanced National CLAS Standards should:

- Expand the target audience beyond health care organizations
- Encompass a broad definition of culture to include religion and spirituality; lesbian, gay, bisexual, and transgender individuals; deaf and hearing impaired individuals; and blind and vision impaired individuals
- Offer more guidance pertaining to language assistance services
- Establish congruency with other related standards in the field.

National Project Advisory Committee

The National Project Advisory Committee (NPAC) of National CLAS Standards Enhancement Initiative is comprised of 36 subject matter experts in the fields of cultural and linguistic competency representing HHS agencies, academic institutions, health associations, and other private organizations. A complete list of NPAC members is available at www.thinkculturalhealth.hhs.gov. The NPAC provided insight, recommendations, and review throughout the development of the enhanced National CLAS Standards. The Enhancement Initiative Project Team conducted informal interviews in fall 2010 with the members of the NPAC to gather input on the enhanced National CLAS Standards from subject matter experts representing a myriad of roles in the field of cultural and linguistic competency. These conversations, along with the public comment and the

systematic literature review, served to begin the laying of the foundation for the enhanced National CLAS Standards in fall 2010. The topics of discussion included the purpose and scope of the future National CLAS Standards, the target audience, and issues surrounding implementation and promotion.

The NPAC convened twice in Washington, DC during 2011. At the January 2011 meeting, the NPAC discussed the following topics in depth: Purpose, Definitions, Inclusivity, Audience, Health Literacy, Language Access Services, Measurements, Implementation, Promotion, and End Product.

The January 2011 meeting built the framework for the Project Team to begin drafting the enhanced National CLAS Standards. During spring 2011, the NPAC reviewed and provided feedback on a document of terminology and definitions that would serve as the conceptual underpinning of the enhanced National CLAS Standards. The NPAC met virtually for a series of webinars in summer 2011 to define the direction of the enhanced National CLAS Standards and discuss draft Standards. Another recurring theme throughout the public comment portion of the National CLAS Standards Enhancement Initiative was the request for additional support and guidance in the implementation and maintenance of the National CLAS Standards. To address this issue, the NPAC began compiling information and materials for the guidance document, *National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care: A Blueprint for Advancing and Sustaining CLAS Policy and Practice (The Blueprint)* to accompany the

enhanced National CLAS Standards. *The Blueprint*, which describes each stage of the development process, is available at www.thinkculturalhealth.hhs.gov.

Systematic Literature Review

The systematic literature review, developed in 2010, discusses the evolution of the efforts to improve cultural and linguistic appropriateness since the publication of the original National CLAS Standards in 2001. It addresses the broad dissemination, promotion, and implementation nationwide of the National CLAS Standards and the concepts of CLAS. In addition, the report covers cultural competency education initiatives; adoption of CLAS at the federal, state, and organizational levels; changes in accreditation standards to explicitly include CLAS; the proliferation of technical assistance regarding CLAS; and research and evaluation of the National CLAS Standards' impact. The report concludes with areas for consideration that emerged from the literature and research of the last 10 years, which provided insight into the issues the enhanced National CLAS Standards should address.

Rationale for the enhancement of the CLAS Standards

The public comments from the online portal, the written submissions, the regional public meetings, systematic literature review, and the NPAC offered a great pool of suggestions on how to enhance the National CLAS Standards. The enhanced *National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care* are composed of 15 Standards that provide individuals and organizations with a blueprint for successfully implementing and maintaining culturally and linguistically appropriate services. Culturally and linguistically appropriate health care and services, broadly defined

as care and services that are respectful of and responsive to the cultural and linguistic needs of all individuals, are increasingly seen as essential to reducing disparities and improving health care quality.

All 15 Standards are necessary to advance health equity, improve quality, and help eliminate health care disparities. As important as each individual Standard is, the exclusion of any Standard diminishes health professionals' and organizations' ability to meet an individual's health and health care needs in a culturally and linguistically appropriate manner. Thus, it is strongly recommended that each of the 15 Standards be implemented by health and health care organizations.

Statement of Intent

In response to public comment and the National Project Advisory Committee feedback requesting further clarification on the intent of the National CLAS Standards, a statement of intent for the enhanced National CLAS Standards was crafted and has been added as an introductory sentence to the Standards:

The National CLAS Standards are intended to advance health equity, improve quality, and help eliminate health care disparities by establishing a blueprint for health and health care organizations to:

As the enhanced National CLAS Standards are disseminated, the inclusion of the statement of intent within the actual Standards ensures that every person who uses the Standards will understand their importance. Although this introductory sentence does not convey the only purpose of the Standards, it does convey their primary goal. The addition of the statement of

intent ties the culturally and linguistically competent policies and practices posed in the enhanced National CLAS Standards directly to the goals of advancing health equity, improving quality, and eliminating health care disparities.

Advance Health Equity

Health equity is defined as the attainment of the highest level of health for all people (HHS OMH, National Stakeholder Strategy for Achieving Health Equity, 2011). Currently, many individuals are unable to attain their highest level of health for several reasons, including social factors such as inequitable access to quality care and individual factors such as limited resources. Lack of health equity has a significant economic and societal impact.

Improve Quality

Culturally and linguistically appropriate services and related education initiatives affect several aspects of an organization's continuous quality improvement initiatives. For example, research suggests that after implementation of CLAS initiatives, there are substantial increases in provider knowledge and skill acquisition and improvements in provider attitudes toward culturally and linguistically diverse patient populations¹. Studies also indicate that patient satisfaction increases when culturally and linguistically

¹ Beach, M. C., Cooper, L. A., Robinson, K. A., Price, E. G., Gary, T. L., Jenckes, M. W., ... Powe, N. R. (2004). Strategies for improving minority healthcare quality. (AHRQ Publication No. 04-E008-02). Retrieved from the Agency of Healthcare Research and Quality website: <http://archive.ahrq.gov/downloads/pub/evidence/pdf/minqual/minqual.pdf>

appropriate services are delivered². At the organizational level, hospitals and clinics that support effective communication by addressing CLAS have been shown to have higher patient-reported quality of care and more trust in the organization³. Preliminary research has shown a positive impact of CLAS on patient outcomes⁴, and a growing body of evidence illustrates the effectiveness of culturally and linguistically appropriate services in improving the quality of care and services received by individuals⁵.

Help Eliminate Health Care Disparities

Eliminating health care disparities is one of the ultimate goals of advancing health equity. Disparities exist and persist across many culturally diverse groups, with individuals who

² Beach, M. C., Cooper, L. A., Robinson, K. A., Price, E. G., Gary, T. L., Jenckes, M. W., ... Powe, N. R. (2004). Strategies for improving minority healthcare quality. (AHRQ Publication No. 04-E008-02). Retrieved from the Agency of Healthcare Research and Quality website: <http://archive.ahrq.gov/downloads/pub/evidence/pdf/minqual/minqual.pdf>

³ Wynia, M. K., Johnson, M., McCoy, T. P., Passmore Griffin, L., & Osborn, C. Y. (2010). Validation of an organizational communication climate assessment toolkit. *American Journal of Medical Quality*, 25(6), 436–443. doi:10.1177/1062860610368428

⁴ Lie, D. A., Lee-Rey, E., Gomez, A., Bereknayel, S., & Braddock, C. H. (2010). Does cultural competency training of health professionals improve patient outcomes? A systematic review and proposed algorithm for future research. *Journal of General Internal Medicine*, 26(3), 317–325. doi:10.1007/s11606-010-1529-0

⁵ Beach, M. C., Cooper, L. A., Robinson, K. A., Price, E. G., Gary, T. L., Jenckes, M. W., ... Powe, N. R. (2004). Strategies for improving minority healthcare quality. (AHRQ Publication No. 04-E008-02). Retrieved from the Agency of Healthcare Research and Quality website: <http://archive.ahrq.gov/downloads/pub/evidence/pdf/minqual/minqual.pdf>.

Goode, T. D., Dunne, M. C., & Bronheim, S. M. (2006). The evidence base for cultural and linguistic competency in health care. (Commonwealth Fund Publication No. 962). Retrieved from The Commonwealth Fund website: http://www.commonwealthfund.org/usr_doc/Goode_evidencebasecultlinguisticcomp_962.pdf

identify as racial or ethnic minorities being less likely to receive preventive health services, even when insured⁶.

Clarity and Action

Each of the National CLAS Standards was revised for greater clarity and focus. In addition, the wording of each of the 15 Standards now begins with an action word to emphasize how the desired goal may be achieved.

Standards of Equal Importance

The original National CLAS Standards designated each Standard as a recommendation, mandate, or guideline. The recommendation (original 14 Standards) was a suggestion for voluntary adoption by health care organizations. The mandates (original Standards 4, 5, 6, and 7) were Federal requirements for all recipients of Federal funds. The guidelines (original Standards 1, 2, 3, 8, 9, 10, 11, 12, and 13) were activities recommended for adoption as mandates by federal, state, and national accrediting agencies.

However, the enhanced National CLAS Standards promote collective adoption of all Standards as the most effective approach to improve the health and well-being of all individuals. The Standards are intended to be used together, as mutually reinforcing actions, and each of the 15 Standards should be understood as an equally important guideline to advance health equity, improve quality, and help eliminate health care disparities.

⁶ DeLaet, D. E., Shea, S., & Carrasquillo, O. (2002). Receipt of preventive services among privately insured minorities in managed care versus fee-for-service insurance plans. *Journal of General Internal Medicine*, 17, 451–457. doi:10.1046/1525-1497.2002.10512.x

Although the enhanced National CLAS Standards are not statutory or regulatory requirements, failure by a recipient of Federal financial assistance to provide services consistent with Standards 5 through 8 (Communication and Language Assistance Standards) could result in a violation of Title VI of the Civil Rights Act of 1964 and its implementing regulations (42 USC 2000d et seq. and 45 CFR Part 80). Therefore, implementation of these goals may help ensure that health care organizations and individual providers serve persons of diverse backgrounds in a culturally and linguistically appropriate manner in accordance with the law. Health care organizations and individual providers are encouraged to seek technical assistance from the HHS Office for Civil Rights or review the *HHS Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons* document (HHS Office for Civil Rights, 2003) to assess whether or to what extent language access services must be provided in order to comply with the Title VI requirement to take reasonable steps to provide meaningful access to their programs for persons with limited English proficiency.

Principal Standard and Three Enhanced Themes:

Principal Standard

Standard 1 has been made the Principal Standard with the understanding that it frames the essential goal of all of the Standards, and if the other 14 Standards are adopted, implemented, and maintained, then the Principal Standard will be achieved.

1. Provide effective, equitable, understandable, respectful, and quality care and services that are responsive to diverse cultural health beliefs and practices, preferred languages, health literacy, and other communication needs.

Theme 1: Governance, Leadership, and Workforce

Changing the name of Theme 1 from *Culturally Competent Care* to *Governance, Leadership, and Workforce* provides greater clarity on the specific locus of action for each of these Standards and emphasizes the importance of the implementation of CLAS as a systemic responsibility, requiring the investment, support, and training of all individuals within an organization.

The Standards in this theme include:

2. Advance and sustain governance and leadership that promotes CLAS and health equity
3. Recruit, promote, and support a diverse governance, leadership, and workforce
4. Educate and train governance, leadership, and workforce in CLAS

Theme 2: Communication and Language Assistance

Changing the name of Theme 2 from *Language Access Services* to *Communication and Language Assistance* broadens the understanding and application of appropriate services to include all communication needs and services, including sign language, braille, oral interpretation, and written translation.

The Standards in this theme include:

5. Offer communication and language assistance
6. Inform individuals of the availability of language assistance
7. Ensure the competence of individuals providing language assistance
8. Provide easy-to-understand materials and signage

Theme 3: Engagement, Continuous Improvement, and Accountability

Changing the name of Theme 3 from *Organizational Supports* to *Engagement, Continuous Improvement, and Accountability* underscores the importance of establishing individual responsibility in ensuring that CLAS is supported, while retaining the understanding that effective delivery of CLAS demands actions across an organization. This revision focuses on the supports necessary for adoption, implementation, and maintenance of culturally and linguistically appropriate policies and services regardless of one's role within an organization or practice. All individuals are accountable for upholding the values and intent of the National CLAS Standards.

The Standards in this theme include:

9. Infuse CLAS goals, policies, and management accountability throughout the organization's planning and operations
10. Conduct organizational assessments
11. Collect and maintain demographic data
12. Conduct assessments of community health assets and needs
13. Partner with the community
14. Create conflict and grievance resolution processes
15. Communicate the organization's progress in implementing and sustaining CLAS.

The past decade has shown that the National CLAS Standards are a dynamic framework.

Therefore, as best and promising practices in the field of cultural and linguistic competence develop, there will be future enhancements of the National CLAS Standards. The HHS OMH also maintains a Web version of *The Blueprint* to provide a more comprehensive and up-to-date resource, with supporting material online at www.thinkculturalhealth.hhs.gov.

Dated: September 11, 2013.

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Office of Minority Health

U.S. Department of Health and Human Services

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